

CLAIMS

What is claimed is:

- Sub C*
1. Apparatus for treating a selected area of the vascular system of a human patient comprising:
5 a) an elongated flexible catheter tube having a proximal end portion adapted to remain outside the patient's body, a distal end portion adapted to be positioned at a selected location within the vascular system of a patient, and a first lumen extending between said proximal end portion and said distal end portion, said catheter tube being of sufficiently small diameter for introduction into the vascular system of a human patient;
- 10 b) a port communicating with said first lumen at said proximal end portion for introducing a blood-compatible liquid thereinto;
- 15 c) a source of blood-compatible liquid in communication with said port for introducing said liquid under pressure into said port; and
- 20 d) a treating element positionable in said first lumen, said treating element being movable from said proximal end portion through said lumen and to said distal end portion of said first lumen by the motive force of the aforesaid liquid flowing through said first lumen.
2. The apparatus of Claim 1, wherein said first lumen is open at said distal end portion, and said apparatus further comprises a retention projection extending into said first lumen at said distal end portion of said first lumen, said projection being
5 adapted to retain said treating element within said first lumen.
3. The apparatus of Claim 1, wherein said elongated tube includes a second lumen extending between said proximal and distal end portions, said second lumen being in communication with said first lumen at said distal end portion, the distal end portions of said first and second lumens being otherwise closed to the exit of fluid whereby fluid moves between said proximal

and distal end portions of said first lumen and returns along said second lumen, and whereby said treating elements are movable between said distal end portion and said proximal end portion of said elongated tube by the motive force of liquid introduced into said second lumen.

5 4. The apparatus of Claim 3, wherein said elongated tube includes a third lumen extending between said proximal and distal end portions, said third lumen being open at both end portions,
10 and being adapted to receive a guide wire for aiding in positioning said elongated tube at the selected area in the body.

5 5. The apparatus of Claim 1, wherein said treating element is a source of radiation.

6. The apparatus of Claim 5, further comprising a pair of spaced apart radiopaque markers located on the distal end portion of said elongated tube and defining the effective treatment area therebetween.

7. The apparatus of Claim 5, wherein said treating element comprises a beta-particle emitting radioactive material.

8. The apparatus of Claim 1, further comprising:
a housing member, said housing member having a first end, a second end and a first bore extending within said housing member from said first end;

5 said elongated tube being attached to said first end of said housing member and said proximal end portion of said first lumen being in communication with said first bore at said first end;

 said housing member being adapted for positioning said treating element within said first bore.

9. The apparatus of Claim 8, wherein said housing member further comprises a gate, said gate being movable between a first position and a second position wherein said treating element is released into said first bore.

10. The apparatus of Claim 1, further comprising:

a fluid pump operatively connected to said first lumen, said fluid pump adapted to control fluid flow through said first lumen.

~~11. A method for treating a selected area of the vascular system of a human patient comprising:~~

a) providing an elongated flexible catheter tube having a distal end portion adapted to be positioned at a selected area in the vascular system of the patient, a proximal end portion adapted to remain outside the body of the patient, a first lumen extending therebetween, and a port communicating with said first lumen at said proximal end portion for introducing a blood-compatible liquid thereinto;

b) introducing the distal end portion of the elongated catheter tube percutaneously into the vascular system of a patient;

c) advancing the distal end portion to a selected position in the vascular system;

d) introducing a treating element into said first lumen of said elongated catheter tube at said proximal end portion of said tube;

e) moving said treating element through said first lumen by flowing a blood-compatible liquid through said first lumen from the proximal end portion to the distal end portion of said tube, said liquid flow generating a motive force on said treating element to move said treating element from said proximal end portion through said lumen to said distal end portion;

f) allowing said treating element to remain at said distal end portion sufficient time for treatment of said selected area, during which time the remaining portion of said elongated catheter tube is free of treating elements; and

g) withdrawing said elongated catheter tube from the body of said patient.

12. The method of Claim 11, wherein said elongated tube further comprises a second lumen extending between said proximal end portion and said distal end portion of said elongated tube, and further including the step of:

5 a) introducing an elongated guide wire having a proximal end portion and a distal end portion opposite said proximal end portion into the selected area of the body prior to introducing said first elongated tube, whereby said distal end portion of said guide wire extends to the selected area; and

10 b) advancing said second lumen of said elongated tube over said guide wire to move said distal end portion of said elongated tube to the selected area in the body.

13. The method of Claim 11, further comprising the step of:

5 a) introducing an elongated guide wire having a first end portion and a second end portion opposite said first end portion, into the selected area of the body prior to introducing said elongated tube, whereby said second end portion of said guide wire extends within the body and to the selected area;

10 b) inserting a guide tube having a proximal end portion, an open distal end portion and a lumen extending therebetween into the patient after introducing said elongated guide wire by advancing said guide tube over said guide wire until said second end portion of said guide tube is positioned within the body proximate the selected area;

15 c) removing said guide wire from said distal end portion of said guide tube; and

 d) advancing said elongated tube into said lumen of said guide tube until said distal end portion of said elongated tube is positioned within the body within said lumen of said guide tube.

14. The method of Claim 11, wherein said treating element is radioactive and including allowing said radioactive treating element to remain at said distal end portion of said first lumen of said elongated tube for a sufficient period of time to expose

the selected area of the body to a therapeutically effective amount of radiation.

15. The method of Claim 14, wherein said therapeutically effective amount of radiation is between 100 and 10,000 rad.

16. The method of Claim 11, further comprising the step of retrieving said radioactive source from said distal end portion of said elongated tube prior to withdrawing said elongated tube from the body of the patient.

~~17.~~ An elongated tube having a proximal end portion, a distal end portion opposite said proximal end portion and a lumen extending therebetween;

an inflatable balloon having a proximal end portion and a distal end portion opposite said proximal end portion; said end portion of said balloon being attached to said distal end portion of said elongated tube; and

a treating element being positioned at said distal end portion of said elongated tube within said balloon.

18. The apparatus of Claim 17, wherein said treating element has a proximal end and a distal end, and further comprising:

a first radiopaque marker located adjacent said distal end of said radioactive element; and

5 a second radiopaque marker located adjacent said proximal end of said treating element.

19. The apparatus of Claim 17 wherein said elongated tube has a second lumen extending between said proximal end portion and said distal end portion of said tube, said second lumen being in communication with said balloon to allow inflation of said balloon when pressurized fluid is introduced therethrough.

~~20.~~ The method
An apparatus for irradiating a selected area of a coronary artery that has been subjected to a balloon angioplasty procedure, comprising:

providing an elongated catheter tube having a distal end portion, a proximal end portion, a first lumen extending therebetween, and a port communicating with said first lumen at said proximal end portion for introducing liquid thereinto;

5 introducing the distal end portion of the elongated catheter tube into the vascular system of a patient and advancing the distal end portion to the selected area in the coronary artery where the balloon angioplasty procedure has been carried out;

10 introducing a radioactive treating element into said first lumen at said proximal end portion of said elongated catheter tube;

15 moving the radioactive treatment element from said proximal end portion to said distal end portion of said elongated catheter tube by introducing a pressurized liquid into said first lumen at said proximal end portion of said tube to generate a motive force on the treating element;

20 allowing the radioactive treating element to remain in the distal end portion of said elongated catheter tube for a time sufficient to expose the selected area of the coronary artery with a therapeutically effective amount of radiation; and

removing the radioactive treating elements from the selected area within the coronary artery.

21. The method of Claim 20 wherein the elongated catheter tube comprises a second lumen extending between said proximal and distal end portions and communicating with said first lumen at said distal end portion for providing a return passageway for liquid employed in moving the radioactive treating element to the distal end portion, and wherein said radioactive treating element is removed from the selected area of the coronary artery by reversing the flow of liquid so that it flows from the proximal to the distal end portion of said second lumen and from the distal to the proximal end portion of said first lumen to provide a motive force for returning the radioactive treating element to the proximal end portion of the elongated catheter tube.

22. The method of Claim 20 wherein the radioactive treating element comprises beta-emitting radioactive material.
23. The apparatus of Claim 8 further comprising a separate carrier for the treating elements, said carrier being adapted for connection with said housing.
24. The apparatus of Claim 23 wherein said housing includes a dispatch passageway for communication of liquid to dispatch the treating elements, guide wire passageway for passage of a guide wire, and a third passage way for return of said liquid through
5 the housing.
25. The apparatus of Claim 1, wherein said treating element comprises a plurality of treating elements flexibly joined in series to form a train of treating elements.
26. The apparatus of Claim 1 wherein the diameter of said first lumen is less than twice the diameter of the treating element.
27. The apparatus of Claim 17 in which the treating elements are fixedly disposed at said distal end portion.
28. The apparatus of Claim 17 wherein said tube includes a lumen extending between said proximal and distal end portions in which said treating elements are movable between said proximal and distal end portions.

add A2